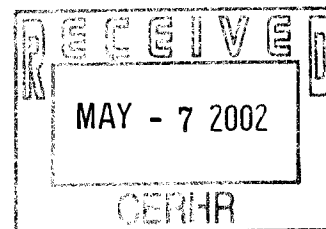


COURTNEY M. PRICE
VICE PRESIDENT
CHEMSTAR



May 6, 2002

Center for the Evaluation of Risks to Human Reproduction (CERHR)
National Toxicology Program
P.O. Box 12233, MD EC-32
Research Triangle Park, NC 27709



Re: Propylene Glycol (CASRN: 57-55-6)

Dear Sir/Madam:

We are writing in response to the National Toxicology Program (NTP) Center for the Evaluation of Risk to Human Reproduction's (CERHR's) March 5, 2002 *Federal Register* notice (67 Fed. Reg. 9980) concerning CERHR's plans to hold an expert panel evaluation of propylene glycol (CASRN: 57-55-6). The American Chemistry Council's Propylene Glycol Panel (Panel), whose members are Huntsman Corporation, Lyondell Chemical Company and The Dow Chemical Company, is pleased to nominate well qualified scientists to serve on the expert panel. The Panel is surprised, however, that NTP has decided to review propylene glycol without following its own priority-setting procedures. By failing to adhere to its own procedures to provide notice, NTP has deprived itself from full consideration of whether a CERHR evaluation of the reproductive and developmental toxicity of propylene glycol is an appropriate use of limited NTP resources and the resources of others involved.

Nominees to Serve on the Expert Panel

The Panel nominates the following well qualified individuals to serve on CERHR's expert panel:

Nominee:

George Daston
Sid Hunter

Joseph Holson
Judy Buelke-Sam
Charles Timchalk
Willem Faber
Edward Carney

Affiliation

Proctor & Gamble
US Environmental Protection Agency (EPA), Office of
Research & Development
Wil Research Laboratories, Inc.
Private Consultant
Battelle Pacific Northwest National Laboratory
Private Consultant
The Dow Chemical Company



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Failure to Follow CERHR's own Priority Setting Procedures

The procedures outlined by CERHR on its web site describe a detailed and, we believe, appropriate procedure for setting priorities within the CERHR program. While we cannot know what review may have occurred internally at CERHR, Steps 6 and 7 clearly were not followed for propylene glycol. Those steps are:

- (6) Notice of candidate chemicals and request for public comment published in the *Federal Register*.
- (7) Public comments are reviewed by the Core Committee and prioritized chemicals are recommended to Associate Director, NTP.

For reasons not explained, CERHR has ignored its own procedures and has moved directly to Step 8 by announcing the selection of propylene glycol and the solicitation of public comment with an approximately sixty-day comment deadline.

By contrast, chemicals reviewed by the last two CERHR expert panels (1-bromopropane, 2-bromopropane, and methanol), as well as ethylene glycol, which was also listed in the same March 5, 2002 *Federal Register* for review, were all included in the "Chemicals Recommended for Further Consideration" notice published for comment two years ago. See 65 Fed. Reg. 14497 (March 20, 2000). The contrast between the handling of these other chemicals and propylene glycol is sharp and demonstrates clearly the failure to follow stated process in the case of propylene glycol.

By failing to follow CERHR's own procedures, NTP has deprived itself of the opportunity to consider whether propylene glycol should be on the priority list. Given the very limited resources available to CERHR and others and the few chemicals that can be reviewed, it is especially problematic to bypass Steps 6 and 7.

Panel Comments on the Proposed CERHR Evaluation of Propylene Glycol

If the Panel had been given the opportunity to comment described in Step 6, the "candidate chemicals" *Federal Register* notice, we would have explained the reasons why we believe CERHR should not use its limited resources to review propylene glycol at this time. In lieu of the opportunity to comment on propylene glycol as a "candidate chemical," those reasons are summarized here.

Propylene glycol is a chemical of very low toxicity having been researched extensively and is "Generally Recognized as Safe" by the Food and Drug Administration. 21 CFR §184.1666. EPA also classifies propylene glycol on Inert List 4B – that is, inert ingredients for

which EPA has sufficient data to substantiate that they can be used safely in pesticide products. 60 Fed. Reg. 35396 (July 7, 1995).

More recently, propylene glycol was reviewed at the OECD's 11th SIAM in January 2001. The approved SIAR includes the following:

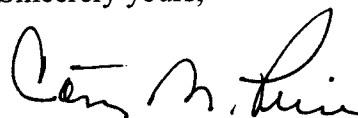
4.2 Human Health Assessment

Propylene glycol does not present an acute, chronic, reproductive, or developmental hazard. Acute toxicity is very low, with LD₅₀ values exceeding 19,000 mg/kg after ingestion or skin contact. It is not a skin or eye irritant, and does not cause sensitization. The weight of the evidence indicates that it is not genotoxic *in vitro* or *in vivo*. Adequate long-term feeding studies are available which indicate that it does not represent a cancer hazard.

The conclusion of the SIAM, representing the view of all the OECD member participants, including the EPA, was: "The chemical is currently a low priority for further work."

Nevertheless, although the Panel questions CERHR's scheduling a detailed review of propylene glycol, we will endeavor to assist NTP in making the review complete and useful. If you have any questions or would like any further information, please contact the Panel Manager, Anne LeHuray, at (703) 741-5630, or anne_lehuray@americanchemistry.com.

Sincerely yours,



Courtney M. Price
Vice President, CHEMSTAR

cc: Propylene Glycol Panel
Dr. John Moore